DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Ethicon Endo-Surgery, Inc.
Ms. Georgia C. Abernathy, MBA, RAC
Senior Regulatory Affairs Associate
4545 Creek Road
Cincinnati, OH 45242

JUL 27 2015

Re: K033269
Trade/Device Name: ENDOPATH® Endocutter Gray Cartridge
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: OCW, GDW
Dated (Date on orig SE ltr): October 8, 2003
Received (Date on orig SE ltr): October 16, 2003

Dear Ms. Abernathy,

This letter corrects our substantially equivalent letter of December 10, 2003.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be

found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K033269

Device Name: ENDOPATH® Endocutter Gray Cartridge

Indications For Use:

The ENDOPATH ETS45 Endoscopic Linear Cutters, the ETS-Flex45 Endoscopic Articulating Linear Cutters, and the ETS Compact-Flex45 Articulating Linear Cutters are intended for transection, resection, and/or creation of anastomoses. The instruments have application in multiple open or minimally invasive general, gynecologic, urologic (including radical prostatectomy), thoracic, and pediatric surgical procedures. They can be used with staple line or tissue buttressing materials such as bovine pericardium.

The ENDOPATH ETS-Flex45 No-Knife Articulating Linear Staplers and the ETS Compact-Flex45 No-Knife Articulating Linear Staplers are intended for transection, resection, and/or creation of anastomoses. The instruments have application in multiple open or minimally invasive general, gynecologic, urologic (including radical prostatectomy), thoracic, and pediatric surgical procedures. They can be used with staple line or tissue buttressing materials such as bovine pericardium.

Prescription Use __X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

(Division Sign-Off) Number K033269

DEC 1 0 2003

K033269

510(k) Summary of Safety and Effectiveness Information

Company Ethicon Endo-Surgery, Inc.
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Date Prepared October 8, 2003

Device Name Trade Name: ENDOPATH® Endocutter Gray Cartridge
Classification Name: Endoscope and Accessories, Implantable Staples

Predicate Device ENDOPATH® Linear Cutters and Staplers

Device Description These instruments are all mechanical surgical stapling devices. The ENDOPATH Linear Cutter models are sterile single use instruments that deliver staples while simultaneously dividing tissue between rows. The ENDOPATH No-Knife Staplers are sterile single use instruments that deliver staples, but do not cut. These instruments may be used in either open or Endoscopic procedures, depending upon the design. Some instruments are Reloadable and, if so, they may be reloaded with various reloads (i.e., vascular/thin, standard, thick) depending on the thickness of tissue that is to be transected or resected.

Indications for Use
The ENDOPATH ETS45 Endoscopic Linear Cutters, the ETS-Flex45 Endoscopic Articulating Linear Cutters, and the ETS Compact-Flex45 Articulating Linear Cutters are intended for transection, resection, and/or creation of anastomoses. The instruments have application in multiple open or minimally invasive general, gynecologic, urologic (including radical prostatectomy), thoracic, and pediatric surgical procedures. They can be used with staple line or tissue buttressing materials such as bovine pericardium.

The ENDOPATH ETS-Flex-45 No-Knife Articulating Linear Staplers and the ETS Compact-Flex45 No-Knife Articulating Linear Staplers are intended for transection, resection, and/or creation of anastomoses. The instruments have application in multiple open or minimally invasive general, gynecologic, urologic (including radical prostatectomy), thoracic, and pediatric surgical procedures. They can be used with staple line or tissue buttressing materials such as bovine pericardium.

Technological Characteristics This is an addition of a gray cartridge reload to this product line. The Gray Cartridge is for use on thin tissue such as mesentery and vessels and has a nominal closed staple height of 0.85mm.

Performance Data Bench testing and pre-clinical laboratory evaluations were performed to demonstrate that the device will perform as intended.